

Plaintiffs ED-GEL, LLC and Thomas J. Harkins, Jr. by way of Complaint against defendants Wells Pharmacy Network, LLC; Wells Pharma, Inc.; Burklow Development, Inc.; Stephen Allen Burklow; William Darian Chandler; Gary Shapiro; Colleen S. Shapiro; and John Doe #1-#99 say:

## **SYNOPSIS**

Plaintiff brings this suit as a result of defendants' trademark infringement, misuse of plaintiff's intellectual property and breach of contract connected with an innovative treatment for erectile dysfunction. Plaintiff contracted to permit defendant Burklow Development, Inc. to make commercial use of plaintiff Harkins' invention (patent pending), his registered trademark, and other intellectual property. Burklow Development, Inc. breached the contract and has failed to account for and pay all the amounts due to plaintiff ED-GEL. In addition, Burklow Development, Inc., with the aid of the individual defendants, transferred plaintiffs' trade secrets to defendant Wells Pharmacy Network, LLC and, on information and belief, to defendant Wells Pharma, Inc. These defendants have and are now infringing on plaintiffs' registered trademark "Tri-Mix Gel", using plaintiffs' trade secrets, and otherwise competing unfairly with plaintiffs. Plaintiffs seek injunctive relief and money damages against defendants.

## **PARTIES**

1. Plaintiff ED-GEL, LLC ("ED-GEL") is a limited liability company organized and existing under the laws of the State of New Jersey and having its New Jersey registered office at 40 North Woodbury Road, Pitman 08071, New Jersey. ED-GEL is authorized to do business under the alternative trade name "TriMix Laboratories, LLC."

2. Plaintiff Thomas John Harkins, Jr. ("Harkins") is an individual residing at 11154 Hall Road, Whaleyville, Maryland 21872. Harkins is the sole owner and Managing Member of ED-GEL.

3. Defendant Wells Pharmacy Network, LLC is a limited liability company of the State of Florida having a place of business at 11120 South Crown Way Suite 11, Wellington, Florida 33414.

4. Defendant Wells Pharma, Inc. is a corporation of the State of Florida

having a principal address at 11120 South Crown Way, Suite 11, Wellington, Florida 33414.

5. Defendants Wells Pharmacy Network, LLC and Wells Pharma, Inc. are affiliates and are collectively referred to in this Complaint as "Wells".

6. Defendant Burklow Development, Inc. ("BDI") is a corporation of the State of Florida having its principal office at 2950 Greystone Drive, Pace, Florida and does or has done business as American Pharmacy Solutions, Inc.

7. Defendant Stephen Allen Burklow ("Burklow") is an individual residing at 2950 Greystone Drive, Pace, Florida 32571. Burklow is or was a shareholder and manager of BDI.

8. Defendant William Darian Chandler ("Chandler") is an individual residing at 5328 Rowe Trail, Pace, Florida 32571. Chandler is the former Chief Operating Officer of BDI and, on information and belief, is currently employed by or affiliated with Wells.

9. Defendant Colleen S. Shapiro is an individual residing or having a principal place of business at 11101 South Crown Way, Suite 5, Wellington, Florida 33414. Colleen Shapiro is the Managing Member of defendant Wells Pharmacy Network, LLC and the President of defendant Wells Pharma, Inc.

10. Defendant Gary Shapiro is an individual residing in the State of Florida and, on information and belief, lives or has offices at 11101 South Crown Way, Suite 5, Wellington, Florida 33414. Gary Shapiro is an owner and manager of defendant Wells Pharmacy Network, LLC and defendant Wells Pharma, Inc.

11. Defendants John Doe #1-#99 (collectively the "Fictitious Name Defendants") are individuals or entities who/that, upon information and belief, have acted in concert with the remaining defendants in relation to the transactions/occurrences upon which the claims asserted by plaintiffs herein are based or who/that have otherwise engaged in unlawful conduct arising out of the

same transactions and/or occurrences as those upon which the claims asserted by plaintiffs herein are based, and the identities of who/which are not known by plaintiffs, including but not limited to the Fictitious Name Defendants and remaining defendants' agents, representatives, heirs, devisees, assigns and other predecessors in interest and successors in interest.

### **JURISDICTION AND VENUE**

12. This Court has jurisdiction over this case under 28 U.S.C. §1331 in that a federal question is raised pursuant to 15 U.S.C. §1051 et. seq. (Lanham Act) specifically, 15 U.S.C. §1114 and 15 U.S.C. §1125. This Court has supplemental jurisdiction under Plaintiffs' claims arising under state law pursuant to 28 U.S.C. §1367.

13. Alternatively, this Court has jurisdiction over Plaintiff's claims arising under state law pursuant to 28 U.S.C. §1332 in that complete diversity is present and the amount in controversy exceeds \$75,000 exclusive of costs.

14. The courts of the District of New Jersey are an appropriate venue for litigation of the claims arising under federal law because one or more acts related to violation of 15 U.S.C. §1114 and 15 U.S.C. §1125 have been committed within the State of New Jersey. In addition, the contract between ED-GEL and BDI which is the basis of plaintiffs' claims arising under State law specifies that disputes shall be brought in a court in the State of New Jersey.

### **FACTS COMMON TO ALL COUNTS**

15. Plaintiff Harkins is a Registered Medical Assistant who managed a urology practice in Cherry Hill, New Jersey for many years during which time he acquired extensive knowledge, training, and clinical experience in the treatment of erectile dysfunction.

16. "Erectile dysfunction" is used herein as the inability to obtain a sexually

functional erection when desired. Millions of men suffer from erectile dysfunction and have sought an effective and pain-free treatment that can be sustained and which presents no dangerous side effects. Known effective treatments include penile implants, penile injection of vasoactive compounds, vacuum-constriction devices, drugs, and intra-urethral vasoactive compounds.

17. For many men, treatment of erectile dysfunction using intra-urethral vasoactive agents is effective and preferable to other therapies. The suitability of intra-urethral treatment is influenced by the side effects of the chemical agents since some are apt to cause the user pain. The treatment has also historically been limited because of the short shelf life of the compounds.

18. Through study and experimentation, Harkins was able to develop a treatment system that overcomes these and other disadvantages.

19. Harkins is the inventor of a "System and Method for Treating Erectile Dysfunction" (the "Invention") that is the subject of U.S. Patent Application 2008/0287879 A1 currently pending. The Invention incorporates a special applicator comprising two interlocking syringes, a penile adapter, carrier gel, and a composition of vasoactive agents the detailed characteristics of which are set forth in the patent application.

20. In practice, the compounding pharmacy inserts a suitable amount of a lyophilized (freeze dried) composition of vasoactive agents and carrier gel separately in two special syringes. By separately storing the ingredients, the shelf life of the vasoactive agents is lengthened. The user mixes the vasoactive agents and carrier gel by means of the coupled syringes which are linked to allow transfer of the vasoactive agents and carrier gel between them. After the syringes are securely locked to each other, the plungers of each syringe are alternately depressed and retracted so that the product within one syringe is transferred to the other syringe. This process is repeated several times to insure that the vasoactive agents and gel become a homogeneous mixture. The result is a gel in which the products are

dissolved completely and are available at full strength for absorption through the mucosa of the urethra. The user then transfers the mixture into the syringe that is configured to accept the bottom portion of a penile adapter. The penile adapter is placed over the meatus of the glans penis. The shape of the penile adapter creates it seal with the meatus so that the homogeneous mixture can be applied to the urethra without any leakage. The shape of the penile adapter also prevents any penetration beyond the meatal opening to prevent pain and discomfort during application.

21. Harkins is the owner of United States Trademark No. 3423866 in the words "TRIMIX GEL" registered on the Principal Register as a mark in International Class 5 (Pharmaceuticals) for "PHARMACEUTICAL GEL FOR THE TREATMENT OF ERECTILE DYSFUNCTION" (the "Trademark").

22. The Trademark was first used in commerce in May 2007; registered on the Principal Register on May 6, 2008; and has been in continuous use since that time. The Trademark is used in connection with the marketing and sale of products embodying the Invention and related products.

23. The Invention is sold in "kits" comprised of a lyophilized composition of vasoactive agents, a carrier gel agent, interlocking syringes and a penile adapter, packaging and package inserts. All components of the kit are as designed by Harkins.

24. The materials as well as the assembly and sale of the kits are regulated by the U.S. Food and Drug Administration as drugs requiring a physician's prescription in order to be sold to the public. To comply with applicable regulations, the ingredients must be prepared and the kits assembled by a licensed compounding pharmacy. The compounding pharmacy receives and fills prescriptions from physicians sending the assembled kits either to the prescribing physician or, more commonly, to the patient himself.

25. Plaintiff ED-GEL is a business entity formed by Harkins for the purpose

of marketing products based on the Invention, licensing the invention to compounding pharmacies, and profiting thereby. ED-GEL also provides information to physicians and to potential users regarding the use of TriMix Gel and its availability at compounding pharmacies.

26. Plaintiff Harkins is the sole member of ED-GEL and has authorized ED-GEL to license and market his intellectual property related to the Invention and the Trademark.

27. As used in this Complaint and unless otherwise limited, "ED-GEL Intellectual Property" is meant to include the Invention and any attendant patent rights in the Invention, the Trademark, the trade name "TriMix" when used in connection with the trademarked products, trade dress used in the authorized sale of TriMix Gel products, trade secrets used in the formulation of TriMix Gel products, and know-how associated with the design, compounding, and other operations involved in the sale of TriMix Gel products.

28. Defendant BDI is a compounding pharmacy having the capability of compounding the TriMix Gel preparations, assembling TriMix Gel kits, and filling prescriptions within the regulatory framework established by the U.S. Food and Drug Administration and the various State boards of pharmacy.

29. Defendant Burklow was at times material to the allegations of this complaint a managing executive of BDI and a person closely involved at BDI in the creation and administration of the contract between BDI and ED-GEL.

30. Defendant Chandler was, at times material to the allegations of this Complaint, the chief operating officer of BDI and the person at BDI who signed the BDI contract on behalf of BDI. On information and belief, Chandler is currently employed by Wells.

31. Defendant Wells is a compounding pharmacy that holds itself out to the public as having the capability of compounding preparations such as TriMix Gel.

**COUNT I**

*(Breach of Contract; Plaintiffs v BDI)*

32. On or about June 30, 2010, ED-GEL (d/b/a TriMix Laboratories LLC) and BDI entered into a written contract whereby BDI was granted a license to compound preparations and fill prescriptions using the ED-GEL Intellectual Property. (the "BDI Contract").

33. The BDI contract requires BDI to:

- a. Fill orders for TriMix Gel kits and take orders via the telephone lines established and promoted by ED-GEL;
- b. Purchase from ED-GEL the applicators needed to fill prescriptions for TriMix Gel kits and use those applicators exclusively in assembling the kits;
- c. Provide ED-GEL with monthly reports of the kits sold and related consumer information;
- d. Maintain ED-GEL's Intellectual Property and customer information in confidence and not disclose it to any third party without prior written consent;
- e. Neither seek nor receive any financial gain from any third party as a result of using ED-GEL's Intellectual Property; and
- f. Return unused applicators to ED-GEL upon termination of the contract.

34. BDI filled prescriptions for kits beginning in July 2010 and extending to about February 2012 for which period it accounted for the orders and paid ED-GEL as contemplated by the contract.

35. Although BDI had sales, it made no payments or reports after February 2012 in breach of the BDI Contract.

36. On information and belief, sometime in early 2012, BDI ceased filling prescriptions for the TriMix Gel kits in breach of the BDI Contract.



37. On information and belief, sometime in early 2012, BDI ceased servicing the ED-GEL telephone lines in breach of the BDI Contract.

38. By letter dated June 27, 2012, Harkins notified Berklow and Chandler that ED-GEL was terminating its contract with BDI because BDI was no longer fulfilling orders as required by the contract between ED-GEL and BDI.

39. On information and belief, sometime between April 2012 and July 2012, BDI and Wells entered into an agreement where all or part of the BDI business was sold to Wells.

40. ED-GEL Intellectual Property was transferred to Wells in connection with said transaction without the knowledge or consent of ED-GEL in breach of the BDI Contract.

41. As a result of the breach of the BDI Contract by BDI, ED-GEL has suffered loss of profit and loss of future business and will continue to suffer such losses in the future. On information and belief, plaintiff's economic damages exceed \$75,000.

WHEREFORE plaintiffs demand of defendant Burklow Development, Inc. compensatory damages not less than \$75,000, interest, attorney fees, costs of this action, and such other damages as this court shall consider just and equitable.

## **COUNT II**

*(Trademark Infringement, 15 U.S.C. §1114(a); Plaintiffs v Wells)*

42. Plaintiffs repeat the foregoing allegations as if set forth fully here.

43. Wells is not a licensee of the Trademark or otherwise authorized to use the Trademark in commerce. Harkins has not consented to permit Wells to use the Trademark.

44. By its express terms of the BDI Contract, the license granted to BDI was limited to BDI and did not extend to any other party unless written consent was

granted by ED-GEL.

45. ED-GEL has not consented to extend the BDI license to Wells nor to permit Wells to use ED-GEL Intellectual Property for preparation of TriMix Gel or for similar products.

46. Without the consent of Harkins, Wells has used the Trademark in commerce in connection with the sale, offering for sale, distribution, or advertising of goods in a manner likely to cause confusion or mistake or to deceive. For example, Wells has offered for sale and sold kits for the treatment of erectile dysfunction under the registered trademark "TriMix Gel" in the State of New Jersey. Plaintiff Harkins knows this because he has caused the product to be ordered from Wells based on Wells' advertisements and had his order filled by shipment to New Jersey.

47. Wells is also offering counterfeits of the TriMix Gel kit for Sale in other States and, on information and belief, is filling orders in other States as well as in New Jersey.

48. Wells is aware that "TriMix Gel" is a registered trademark because, among other things, it reproduces the circled "R" registration mark on the packaging, package inserts and order forms.

49. Wells is aware that it does not have authorization to use the Trademark because, among other things, Harkins told defendant Gary Shapiro in a meeting at which Harkins, Shapiro, and Chandler were present on or about January 11, 2012 that a separate license would be required before Wells could use the ED-GEL Intellectual Property including the Trademark.

50. Wells has willfully infringed the Trademark and is continuing to infringe.

51. ED-GEL and Harkins have been damaged by the loss of sales from the TriMix Gel products and consumer confusion resulting from the infringement of the mark.

WHEREFORE plaintiffs demand an order enjoining Wells from continuing to use the Trademark in commerce without the express consent of plaintiffs, return of materials required by the BDI Contract, compensatory damages, treble damages in accordance with 15 U.S.C. §1117, attorney fees, costs of this suit, and such other relief as this court shall consider just and equitable.

### **COUNT III**

*(False Designation of Origin, 15 U.S.C. §1117; Plaintiffs v Wells)*

52. Plaintiffs repeat the foregoing allegations as if set forth fully here.

53. In connection with its marketing, sale, and distribution of its erectile dysfunction treatment kits Wells has used and continues to use counterfeits of the packages created and used by ED-GEL and substantially exact copies of the order sheets and package inserts created and used by ED-GEL in connection with the kits authorized by ED-GEL

54. Such use constitutes a false designation of origin within the meaning of 15 U.S.C. §1125 in that it is likely to confuse and deceive consumers and to cause confusion as to the affiliation or association of Wells with plaintiffs.

55. Plaintiffs have been damaged by such false designations by Wells and are likely to be damages in the future.

WHEREFORE plaintiffs demand an order enjoining Wells from continuing to use the Trademark in commerce without the express consent of plaintiffs, compensatory damages, treble damages in accordance with 15 U.S.C. §1117, attorney fees, costs of this suit, and such other relief as this court shall consider just and equitable.

### **COUNT IV**

*(Trade Secret Misappropriation; Plaintiffs v. All Defendants)*

56. Plaintiffs repeat the foregoing allegations as if set forth fully here.

57. Although the substances used in the creation of the legitimate TriMix Gel products and their effects are generally known, the methodology and the exact formula that renders the products effective while reducing side effects is not generally known and is important in distinguishing TriMix Gel from its competitors.

58. Said formulae and methods are maintained confidential by Harkins and ED-GEL and constitute trade secrets within the meaning of both the New Jersey Trade Secrets Act, N.J.S.A. 56:15-1 et seq. and the Florida Uniform Trade Secrets Act, Fla.Stat. §688.001 et seq.

59. Of necessity, said trade secrets were disclosed to BDI in order to permit BDI to carry out its responsibilities under the BDI contract. Accordingly, the BDI Contract provided that said methodologies and formula comprise confidential information and are not to be disclosed to any third party without the consent of ED-GEL.

60. Without obtaining permission and in order to seek economic advantage for itself BDI, through its agents including Burklow and Chandler, disclosed the formula and methodologies to Wells.

61. Wells, through its agent Gary Shapiro, was aware that ED-GEL considered the said confidential information to be in the nature of a trade secret prior to its transfer to Wells.

62. The transfer of said trade secrets by BDI and its agents to Wells and its agents is a violation of the New Jersey Trade Secrets Act and the Florida Uniform Trade Secrets Act.

63. Plaintiffs have been damaged by the unauthorized disclosure of the trade secrets in that they have lost profits, suffered damage to their business reputation, and lost market share as a result of unauthorized use by Wells.

64. BDI, Burklow, and Chandler have been unjustly enriched by the transfer

of the trade secrets to Wells.

65. The misappropriation of plaintiffs' trade secrets was willful on the part of all defendants.

WHEREFORE plaintiffs demand an order enjoining defendants from using or further disclosing plaintiffs' trade secrets, compensatory and punitive damages, interest, attorney fees, costs of this action, and such other damages as this court shall consider just and equitable.

### **COUNT V**

*(Unfair Competition; ED-GEL v. Wells and BDI)*

66. Plaintiffs repeat the foregoing allegations as if set forth fully here.

67. On information and belief, BDI has permitted Wells access to and the use of formulae, customer lists, and other of ED-GEL Intellectual Property in violation of the confidentiality provisions of the BDI contract.

68. On information and belief, BDI and Wells have diverted business away from ED-GEL by the unauthorized use of ED-GEL Intellectual Property and the mismanagement of the telephone lines that were supposed to be managed by BDI under the BDI contract.

69. Together with past and continuing infringement of the Trademark and the use of plaintiffs' trade secrets, such conduct on the part of Wells and BDI constitutes unfair competition under the laws of the State of New Jersey and other States in which Wells has sold its kits.

WHEREFORE, plaintiffs demand of Wells and BDI disgorgement of profits, exemplary damages sufficient to deter such conduct in the future, interest, attorney fees, costs of this action, and such other damages as this court shall consider just and equitable.

**COUNT VI**

*(Civil Conspiracy; Plaintiffs v. All Defendants)*

70. Plaintiffs repeat the foregoing allegations as if set forth fully here.

71. Defendants herein have pursued a common plan to compete unfairly against plaintiffs through either their active participation in the plan or by ratification of the wrongs committed for their benefit.

72. Plaintiffs have been injured by the wrongs committed in furtherance of defendants' common plan through loss of profits as well as loss of current and prospective business opportunity.

WHEREFORE, plaintiffs demand of defendants compensatory and punitive damages, interest, attorney fees, costs of this action, and such other damages as this court shall consider just and equitable.

**LOCAL CIVIL RULE 11.2 CERTIFICATION**

Pursuant to Local Civil Rule 11.2, I certify that the within matter in controversy is not, to the best of my knowledge, information, and belief the subject of any other action pending in any court, arbitration, or administrative proceeding.

**JURY DEMAND**

Plaintiffs demand trial by jury on all issues so triable.

THE CORBETT LAW FIRM  
Attorney for Plaintiffs

/s/ John E. Corbett

Date: September 27, 2012

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